

REMARKS

Applicant acknowledges with appreciation Examiner Chen's courtesy call prior to the issuance of the Notice of Panel Decision from Pre-Appeal Brief Review to indicate the allowable subject matter of claims 3 and 4.

Applicant also thanks Examiner Chen for granting the follow-up telephonic interview with the undersigned on August 20, 2010, during which a proposed amendment for combining claim 1 and 4 was discussed to place the application in condition for allowance.

This amendment adds the features of claim 4 to claim 1, and, thus, is believed to place the application in condition for allowance. An RCE is being filed with this response, as is required to re-open prosecution.

Status of the Claims

Claim 1 is amended to include the features of claim 4.

Claim 2 is amended to correspond to the changes to claim 1.

Claim 4 is canceled.

Claims 1-3, 5, 7 and 8 remain pending in the application.

**Claim Rejections-35 USC §103(a)**

Claims 1-4 stand rejected under 35 USC §103(a) as being unpatentable over FOSTER, TANEJA et al. U.S. 5,629,351 (TANEJA), RONZIO et al. U.S. 5,762,936 ("RONZIO"), CHARTERS et al. U.S. 6,541,045 ("CHARTERS"), SATO et al. 1967 ("SATO"). This rejection is respectfully traversed for the reasons that follow.

Claim 1 now includes the amounts recited in claim 4.

FOSTER was offered for teaching treating rheumatism and inflammation using saligenin.

TANEJA was offered for teaching that the gum resin of *Boswellia serrata* has been used for the treatment of arthritis at 10g in a range from 1-55% by weight of a composition.

RONZIO was offered for teaching a phenolics content from about 1-6 mg of catechins, which contain procyanidin, for treating inflammation. The Official Action noted that procyanidin may be isolated from green tea leaves. The Official Action apparently intended to propose that one of ordinary skill would have been motivated to isolate procyanidin from green tea leaves.

CHARTERS was offered for teaching an anti-inflammatory drug having N-acetyl D-glucosamine.

SATO was offered for teaching anti-inflammatory activity of D-glucuronolactone.

The maintained position was that it would have been obvious to combine the ingredients above-listed ingredients

because these ingredients were disclosed for the purpose treating inflammation.

However, the claims are unobvious over the combination for at least the following three reasons:

I. Neither an effect nor an amount of procyanidins is taught.

RONZIO was offered for teaching procyanidins, and the maintained position was that one ordinary skill would have been motivated to isolate procyanidin from green tea leaves.

However, RONZIO discloses a lentil husk extract effective for treating inflammation. The extract comprises a phenolics mixture. The phenolic mixture includes 1 to 6 mg of catechin equivalents per 10 milligrams of the extract. This phenolics mixture comprises kaempferol, quercetin, proanthocyanidins and phenolic acids. The proanthocyanidins "include" procyanidins, but at least 50%, and preferably at least 70% of the proanthocyanidins, are in the form of prodelphinidin (abstract, column 5, lines 25-65). Accordingly, one cannot determine an amount of procyanidins present in the lentil husk extract.

Thus, RONZIO fails teach or suggest:

- an amount of procyanidin, let alone procyanidins from *Vitis vinifera* or from *Camellia sinensis* (e.g., green tea extract), and
- any use of procyanidin.

Accordingly, it is without factual basis to conclude that one of ordinary skill in the art would have been led to derive procyanidin from green tea leaves in order to obtain the anti-inflammatory effect of the lentil husk extract of RONZIO.

II. There is no suggestion to optimize.

RONZIO fails to disclose either an amount or an effect of the procyanidins, from either lentil husk or green tea.

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Thus, there is no factual basis to conclude that the amount of procyanidins in a green tea extract, to be combined with other ingredients, would have been a result effective parameter that one would routinely optimize to arrive at the amount recited in claim 1 or the ratio in claim 3.

III. There is no recognition of a synergistic effect.

The declaration filed July 13, 2007 demonstrated that the compounds have a synergistic effect when administered in combination for treating patients suffering from osteoarthritis

of the knee. A corrected declaration was included in the appendix of the amendment filed July 13, 2009.

The composition of Example 1 from the specification, i.e., evaluated in Group 7 of the declaration, demonstrated an increased/synergistic effect of the five active compounds for the reasons explained in the declaration and section IV of the Amendment filed July 13, 2009.

The compounds in the composition of Example 1 were administered within the range of the amounts recited in claim 1 and at a ratio consistent with claim 3.

None of FOSTER, TANEJA, RONZIO, CHARTERS and SATO, or any combination thereof, suggests the synergistic effect demonstrated for the claimed invention.

Therefore, for at least the three reasons discussed above, the proposed combination fails to render obvious claims 1-3, and withdrawal of the rejection is respectfully requested.

Claims 1-5, 7 and 8 stand rejected under 35 USC §103(a) as being unpatentable over FOSTER, TANEJA, RONZIO, CHARTERS, SATO, as applied to claims 1-4, further in view of CHILTON U.S. 6,107,334 ("CHILTON"). This rejection is respectfully traversed for the reasons that follow.

FOSTER, TANEJA, RONZIO, CHARTERS and SATO were offered for the five reasons discussed above.

CHILTON was offered for teaching dietary supplements for ameliorating inflammatory disorders. However, regardless of the ability of CHILTON to teach that for which it was offered, CHILTON does not remedy the shortcomings of FOSTER, TANEJA, RONZIO, CHARTERS and SATO for reference purposes.

Therefore, this combination fails to render obvious claims 1-3, 5, 7 and 8, and withdrawal of the rejection is respectfully requested.

**Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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